Pneupac® babyPAC™ 100 Ventilator

ON-SITE MAINTENANCE PROCEDURE

LEVEL ONE: PERIODIC PERFORMANCE CHECKS

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SECTION 1: IMPORTANT GENERAL INFORMATION

a) General

The safety precautions given in this Section are to be seen as a guide only and are not intended to be a comprehensive list.

i) Qualified persons

Persons servicing and repairing Pneupac ventilators and regulators must be adequately trained and certified by the manufacturer for this task and must be fully conversant with the relevant contents of the User's Manual supplied with the equipment. Engineers must perform service repair and testing of equipment in line with both Health and Safety at Work regulations and their own employer's procedures and observe the appropriate precautions necessary when handling pressurised gases.

This Maintenance Procedure should be read fully before commencing servicing and testing.

ii) Frequency of Checking

Regular performance checking of the babyPAC 100 ventilator must be carried out with equipment calibrated to ensure accuracy under the flow patterns generated by the ventilator.

The user should determine the frequency of periodic checks dependent upon the intensity of use. Normally this would be not more often than once every 6 months but at least once every 2 years.

iii) Oxygen Safety

WARNING: Oil, grease or combustible lubricants, other than those approved for oxygen service, must never be allowed to come into contact with the parts of the ventilator, oxygen regulator, cylinder, repair tools or repair surfaces used in the servicing of this equipment. Particular care should be taken to avoid any trace of contamination around the oxygen inlet and outlet ports of the ventilator. Oil or grease oxidise readily and in the presence of oxygen will burn violently.

Regulator assemblies must not be immersed in liquid at any time.

iv) Note to Service Engineers

It is the responsibility of the customer to present the equipment in a fit condition for use and therefore servicing (if this is not your responsibility). This should enable you to quickly assess the condition of the equipment overall and any obvious damage.

v) MRI

When the ventilator is being used/or likely to be used in an MR Environment, it is important that only MR Compatible spares or accessories are used. This must be checked as part of the on- site maintenance procedure.

vi) CE Marking

The babyPAC 100 ventilators described in this manual carry a CE mark to certify that they have been manufactured to conform to the requirements of the European Medical Devices Directive 93/42/EEC. To ensure that this equipment is maintained to the requirements of the Directive only accessories, ancillaries and spares authorised by the manufacturer should be fitted. All such parts sold by Smiths Medical International Ltd. have /CE incorporated in their order code. Parts that are not marked with /CE are only for sale outside the countries bound by the Directive.

b) Safety Information For Medical Gas Cylinders

1) The warnings on the previous page relating to the use of oxygen are particularly relevant to gas cylinders and cylinder pressure regulators.
2) All personnel handling medical gas cylinders should have adequate knowledge of the properties of the gas, the precautions to be taken and the correct operation of the equipment.
3) Check the cylinder for the name of the gas and the colour code to ensure that the correct cylinder is being used.
4) Before using a cylinder check that it and its valve are in good condition. If there appears to be any damage do not use it.
5) All cylinders are fitted with a colour coded ring on the valve stem showing when it is due for inspection or test. Check that the cylinder is within date. If not do not use it.
6) Completely remove the disposable plastic seal from the valve. Open the valve momentarily to blow any contamination out of the valve outlet. Ensure that the outlet is not directed towards any person.
7) Ensure that the connecting faces on the cylinder and the regulator or fitting are clean and free from scoring or damage.
8) The regulator or fitting can now be attached, using only a reasonable amount of effort to tighten the connection. Never use a hammer or lever.
9) Always open the cylinder slowly.
10) Always close the cylinder valve fully before disconnecting the regulator assembly and fit a cap or tape to the cylinder valve outlet to keep it clean.

SECTION 2: TEST SCHEDULE FOR PERIODIC CHECKING OF babyPAC 100

1 **Record**
2 **Check the condition of the Input Hoses**
3 **Check the condition of the babyPAC**
4 **Check function of alarms and indicators**
5 **Carry out lock off leak test to input supply connections**
6 **Check the Function Selector switch**
7 **Check calibration of Inspiratory (TINS) and Expiratory (TEXP) Time controls**
8 **Check calibration of PEEP & CPAP Pressure control**
9 **Check calibration of Inspiratory Pressure control**
10 **Check calibration of Oxygen Concentration control on CMV with oxygen supply only**
11 **Check calibration of Oxygen Concentration control on CPAP with oxygen and air supply**
12 **Check calibration of Audible High Pressure Alarm control**
13 **Check the condition and security of mounting box, brackets, clamps and pole mounts**
14 **Attach Service Label**
15 **Report non-critical faults to customer**
16 **Report critical faults to the customer**
17 **Obtain an acceptance signature on the Service Record Sheet where applicable.**

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babyPAC 100 PERFORMANCE RECORD SHEET								**SHEET 1 OF 2**
CUSTOMER ORDER:-				REPORT NO:-				
UNIT LOCATION:-				babyPAC 100 SERIAL NO.				
INVOICE ADDRESS:-								
TELEPHONE NO:-				DATE OF SERVICE:-				
TYPE OF SERVICE PROVIDED:-								
ROUTINE		CALL OUT		REPAIR				

TEST SCHEDULE CHECK LIST:-																			
1		2		3		4		5		6		7		8		9		10	
11		12		13		14		15		16		17							

REMARKS:-

ENGINEER'S SIGNATURE ACCEPTANCE SIGNATURE

PRINT NAME

PARTS USED FOR REPAIR

QTY	DESCRIPTION	PART NO	PRICE

TOTAL PARTS COST:-

babyPAC 100 SERVICE RECORD SHEET		SERIAL NUMBER No	
OXYGEN REGULATOR SERIAL No.		AIR REGULATOR SERIAL No.	
(1) QUALIFIED PERSON:-		SIGNATURE:-	DATE :
(2) CHECK CONDITION OF THE INPUT HOSES.		OK / FAIL - REASON:-	
(3) CHECK CONDITION OF CONTROL MODULE.		OK / FAIL - REASON:-	
(4) CHECK FUNCTION OF GAS SUPPLY INDICATORS & ALARMS	OXYGEN	OK / FAIL	AIR OK / FAIL
(5) CARRY OUT LOCK OFF LEAK TEST TO GAS INPUT SUPPLY (MAXIMUM 3 PSI IN 30 SECONDS)	OXYGEN	OK / FAIL	AIR OK / FAIL

(6) CHECK FUNCTION OF THE SELECTOR SWITCH

Position	OFF		CMV+PEEP		CMV + ACTIVE		CPAP		IMV+CPAP	

(4) CHECK ALARM FUNCTIONS

POWER SHUT DOWN	OK / FAIL	LOW PRESSURE DISCONNECT	OK / FAIL
SINGLE GAS OPERATION	OK / FAIL	LOW BATTERY	OK / FAIL
SUPPLY GAS FAILURE	OK / FAIL	HIGH PRESSURE	OK / FAIL
SINGLE GAS ACKNOWLEDGE	OK / FAIL	CONSTANT POSITIVE PRESSURE	OK / FAIL
CYCLE	OK / FAIL	CONSTANT POSITIVE PRESSURE ACKNOWLEDGE	OK / FAIL

(7) CHECK CALIBRATION OF INSPIRATORY (T_{INS}) AND EXPIRATORY (T_{EXP}) CONTROLS

SETTING		ON OXYGEN ONLY @ 100% CONCENTRATION PEEP=0, PEAK=30, VRV=80						ON AIR @ 21% CONCENTRATION PEEP=0, PEAK=30, VRV=80					
Tins	Texp	**CMV** Tins TOL	**CMV** Tins ACT	**CMV** Texp TOL	**CMV** Texp ACT	**IMV** Texp TOL	**IMV** Texp ACT	**CMV** Tins TOL	**CMV** Tins ACT	**CMV** Texp TOL	**CMV** Texp ACT	**IMV** Texp TOL	**IMV** Texp ACT
0.25	0.25	0.34/0.17		0.35/0.17		3.50/1.675		0.33/0.15		0.33/0.15		3.33/1.50	
0.75	0.75	0.90/0.65		0.90/0.65		9.00/6.525		0.85/0.60		0.85/0.60		8.48/6.00	
2.00	4.00	2.40/1.74		4.80/3.48		48.00/34.80		2.26/1.60		4.52/3.20		45.20/32.00	

(8) & (9) CHECK CALIBRATION OF PRESSURE CONTROLS

PEEP /CPAP ON OXYGEN (Tins & Texp=0.5, VRV=80, PEAK=70)
Max difference PEEP to CPAP 5 cmH2O, ACTIVE PEEP TO CPAP 2 cmH2O

SETTING	TOL PEEP	ACT PEEP	TOL ACTIVE PEEP	ACT ACTIVE PEEP	TOL CPAP	ACT CPAP
MIN STOP 0	0		MAX 3		MAX 3	
DETENT 10	15/5		MAX 16		MAX 16	
MAX STOP 20	25/15		MAX 26		MAX 26	

CALIBRATION OF INSPIRATORY PRESSURE ON OXYGEN (Tins=2.0, VRV=80 , PEEP=0)

SETTING	TOL	ACT O_2 ONLY MASTER GAUGE	ACT O_2 ONLY PAC GAUGE	ACT O_2 & AIR MASTER GAUGE	ACT O_2 & AIR PAC GAUGE
MIN STOP 12	17/7				
20	25/15				
DETENT 40	45/35				
MAX STOP 70	75/65				

OXYGEN CONCENTRATION CONTROL CALIBRATION CHECK ON 20 cmH_2O BACKPRESSURE

(10) OXYGEN ONLY SUPPLY ON CMV

SETTING	TOL	ACT Tins 2.0 Texp 4.0	ACT Tins 0.25 Texp 0.25
MIN STOP	50/42		
60%	65/55		
80%	85/75		
MAX STOP 100%	100/95		

(11) OXYGEN & AIR SUPPLY ON CPAP

SETTING	TOL	ACTUAL (20 cmH2O)
MIN STOP 21%	26/21	
MAX STOP 70%	75/67	

(12) VARIABLE RELIEF VALVE PATIENT PRESSURE ALARM CALIBRATION CHECK

SETTING	12	20	30	40	50	60	70	80
TOLERANCE	17/7	25/15	35/25	45/35	55/45	65/55	75/65	85/75
ACTUAL								

SECTION 3: PROCEDURE FOR PERIODIC CHECKING OF babyPAC 100

1. Record

Record Qualified Person's details. Record the serial number of the babyPAC 100 from the label on the rear of the control module and the serial number(s) of the regulator body(ies).

2. Check the condition of the Input Hoses

i) From 1st January 2002 pressure hoses are date coded and should be replaced after 6 years. Check the label on hose for replacement date.

ii) Check that there is no internal damage to the hose by feeling the rigidity of the hose and looking for sloppiness.

iii) Ensure there is no delamination of the hose and no blisters or bubbles on the surface (check again when the hose is pressurised).

iv) Check union ends for signs of kinking and/or damage to hose or union.

v) Replace hose if any of above is apparent.

3. Check the condition of the babyPAC 100

i) Check the Control Module looking for damage to the gauge and surround, the gas supply indicators, the gas input and output fittings, the control knobs, the case and labels.

ii) Check that input and output connections are secure. Tighten if necessary

iii) Check that the input connector filters are clean.

iv) Check that the air intake filter is clean, unblocked and secure. Tighten if necessary.

v) If any of the filters is dirty it should be replaced.

a) First remove the relevant connector and seal from the Control Module.

b) The oxygen supply and air intake filters can be replaced by removing the O-ring (W5520).

c) The conical filter (W9151) should now be pushed from the connector.

d) Both O-ring and filter should be replaced.

e) The air input connector has a retaining circlip holding both O-ring and disc filter.

f) Drive the filter, O-ring and circlip out of the fitting using a 5mm punch.

g) Fit new disc filter (W9158) and O-ring (W5523)

h) Insert a new special retaining circlip (W6487) pushing it down onto the face of the O-ring using a 6mm punch.

i) Refit the connector/s with a new sealing washer (W5582/MRI).

vi) Check that the control knobs move smoothly, are not loose on spindles and do not rub on the front panel. If spindles are bent the knob may rub on the faceplate on one side only.

vii) Check that the knob caps are affixed firmly to the knob, align with the index mark on the knob side, and cannot be rotated, relative to the knob, during normal operation.

viii) Rotate each knob to its extreme limits to verify that the knob has not moved on its spindle.

ix) The T_{INS} and the T_{EXP} knobs should align exactly with both ends of the calibration marks, i.e. at 0.25, 2.0 seconds for T_{INS}, and 0.25, 4.0 seconds for T_{EXP}.

3. Check the condition of the babyPAC 100 (continued)

x) The O_2 concentration knob index mark should be equally spaced from each end of the yellow calibration scale.

xi) PEEP/CPAP and Inspiratory controls should align closely with the calibration marks at the extreme positions but should also just enter the red segment of the calibration mark when each knob initially comes into contact with the rumble strip at their intermediate positions.

xii) The Pressure Alarm control knob should align with the extremes of the calibration marks.

xiii) The dot on the Function Selector switch should align with the marks on the panel at each selection and there should be no intermediate positions.

xiv) If the index mark on any knob side or the cap end is misaligned it should be corrected before further calibration checks are carried out.

xv) To relocate the knob position for controls (except the Pressure Alarm and Function Selector) first remove the end cap from the knob.

xvi) Turn the knob nearly to the end stop at which it is at its maximum height above the panel (timer controls at minimum time, pressure controls at maximum pressure and O_2 Concentration control at 100%) in order to minimise possible needle/seat contact during knob removal.

xvii) Using an appropriate collet spanner (e.g. 500-82073) and supporting the knob by hand in order to minimise any axial thrust on the spindle, release the knob from the spindle.

xviii) Set the T_{INS} and T_{EXP} spindles against their 0.25 second stops and replace the knobs onto the spindles.

xix) Maintaining a gap to the face panel of 0.4/0.5 mm and correct alignment at the 0.25 second calibration, gently retighten the knob collet using only a rotary action. Check that the knobs align with the scale at both ends.

xx) Rotate the knobs until they are just backed-off from the maximum time stop and then tighten the collet screw as tightly as possible with recommended tool (500-82037) while simultaneously supporting the knob by hand to minimise the force applied to the spindle.

xxi) Repeat the above procedure for the O_2 Concentration control but using a minimum gap to the panel of 0.4/0.5mm and making the initial settings at the minimum concentration calibration. Check that the knob is located as in x) above. Finally tighten just short of the maximum calibration position.

xxii) Finally repeat the above procedure for the PEEP/CPAP and Inspiratory Pressure controls but making the initial settings at the minimum pressure calibration. Check that the knobs are located as in xi) above and then finally tighten just short of the maximum pressure settings.

xxiii) With the knobs in the final re-tightening position refit the knob cap ensuring the line on the cap aligns with the line on the side.

xxiv) The Pressure Alarm and Function Selector switch knobs have a fixed location but the cap can be relocated on the front of the knob if the indication is incorrect.

xxv) If the caps on the above knobs have been removed for relocation or can be rotated, relative to the knob, during normal operation they should be secured to the knob with a very small drop of adhesive (DS354 C10/Loctite Prism 460).

xxvi) Check that the gauge surround is secure, the front panel label is secure and not damaged (e.g. punctured) and the silencing button is undamaged.

xxvii) Check that the gauge is in the correct vertical position and has not rotated in the shroud.

3. Check the condition of the babyPAC 100 (continued)

xxviii) Remove the existing battery and check when battery was last changed. If 12 months or more has elapsed, insert a new battery of the correct type (part no. W269-023). If service interval is less than 12 months, mark the battery, or service log for the ventilator, with the date of replacement.

xxix) Replace any damaged labels.

xxx) Check that any accessories or spares added are MR Compatible.

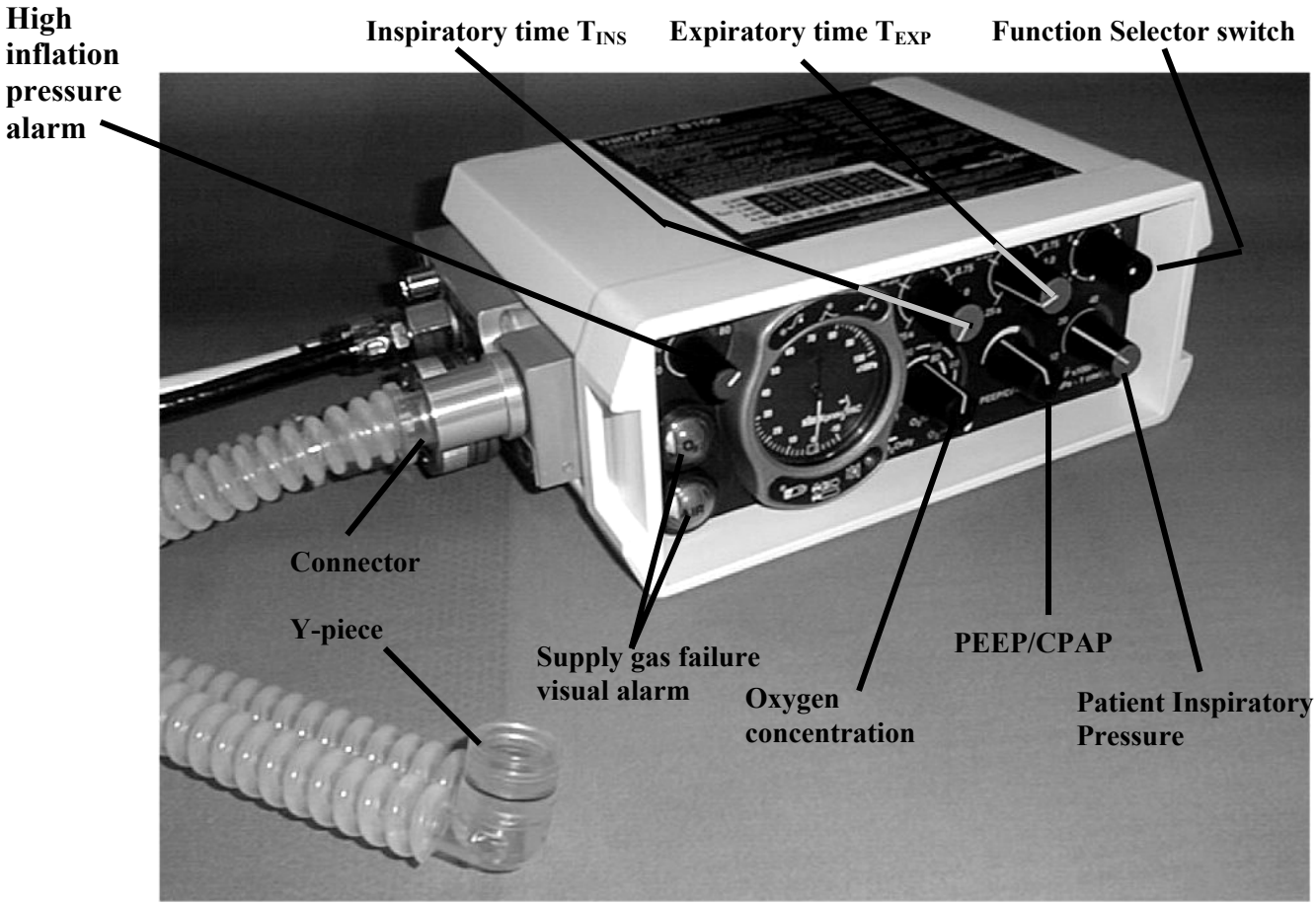

Figure 1: Controls and fittings of the babyPAC 100 ventilator

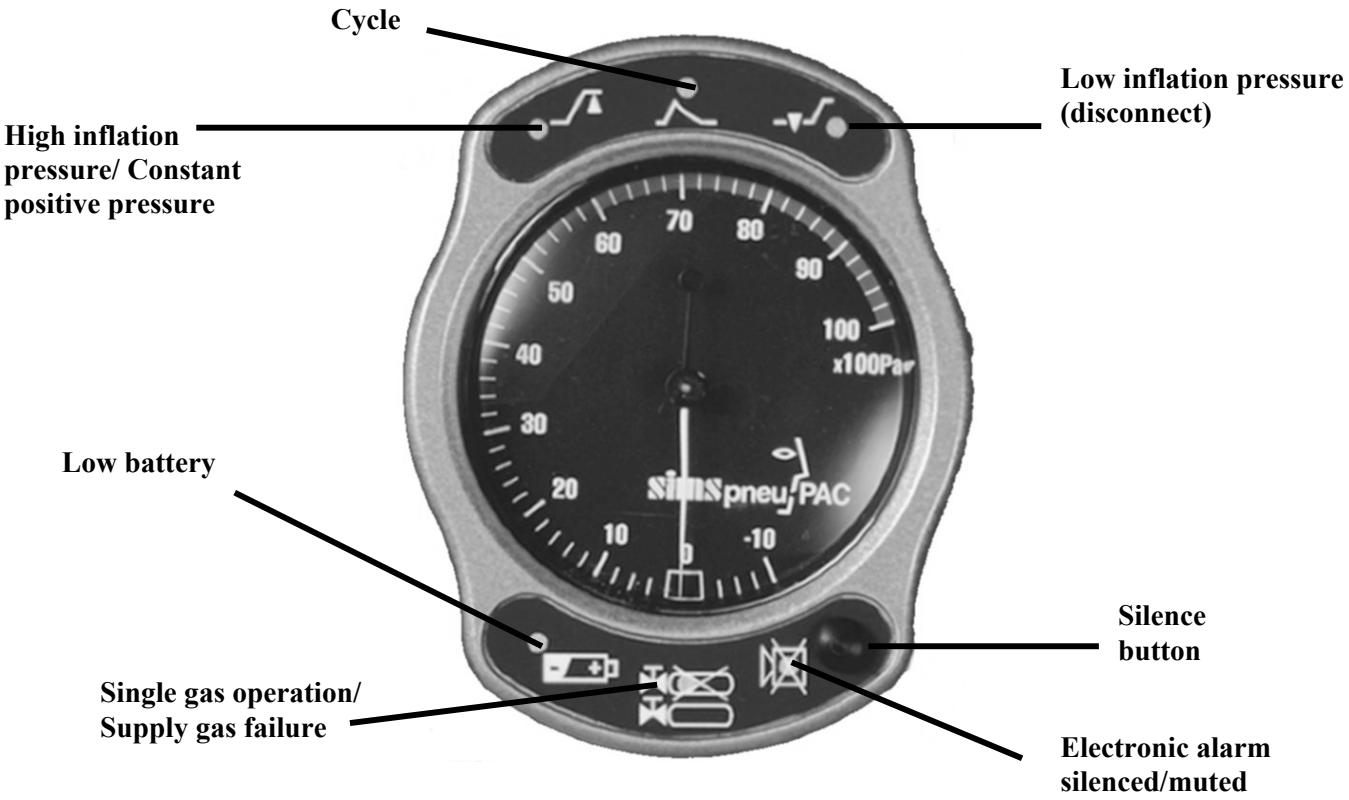

Figure 2 : Alarm Indicators

4. Check function of alarms and indicators
(refer to Figure 2)

i) Set the Function Selector to '0'.

ii) Without a gas supply connected to the ventilator, select CMV + PEEP.

iii) The gas supply indicators will stay red but the alarm LEDs will flash in sequence, starting bottom left and rotating in a clockwise direction. After all 6 LEDs have flashed a Medium Priority alarm will sound and continue for 1 minute. If the ventilator is still left switched on the alarm system will shut down.

iv) With the air and oxygen input hoses connected to the ventilator, connect the hose probes to appropriate gas supplies (minimum requirement 20L/min at 305kPa ≈ 3 bar).

v) Connect a C0.5 R100 ISO Test Lung (500 - 84250) to the Patient Connection Port of the Patient Circuit.

vi) Turn on the air supply and the lower supply gas failure visual alarm should change from red to quartered white and black. Repeat for the oxygen supply; the upper alarm turning from red to white.

vii) Set both the Oxygen Concentration and the PEEP/CPAP controls to minimum.

viii) Select CMV + PEEP on the Function Selector switch. The ventilator should now begin to cycle and the alarm LEDs will go through the test sequence described in iii). The yellow 'silenced' LED (bottom right) should flash but no sound should be generated for 60 seconds. The 'cycle' LED should flash for 1/10 second each time the pressure rises through 10 x100Pa (10 cmH2O).

ix) Turn off the air supply. As the supply depletes, the air supply gas visual alarm should change to red. A medium priority electronic audible alarm giving a burst of three pulses 6 times a minute should then sound for 60 seconds to indicate a supply failure and the 'single gas operation' LED should illuminate in bursts of three flashes every 30 seconds.

4. Check function of alarms and indicators (continued)

(refer to Figure 2)

When the air supply is depleted the ventilator may pause but will then continue to operate on the oxygen supply. If the ventilator fails to change over it should be returned to the manufacturer for repair.

x) Depress the Silence/Mute button and the electronic audible alarm should silence for 60 seconds. After this 60-second period has elapsed, depress the button again and the audible alarm will now remain muted, the second depression being interpreted as an acknowledgement by the operator that single gas operation has been recognised. The 'single gas operation' LED will continue to operate to indicate this mode.

xi) Set the Oxygen Concentration control to its maximum (100%) position.

xii) Turn off the oxygen supply.

xiii) Repeat step ix) above but this time the oxygen supply gas failure visual alarm should change to red and the audible alarms should sound. After 60 seconds the alarm system should switch itself off in order to protect the battery if the ventilator is left in a potential alarm condition after use.

xiv) Select '0'.

xv) Turn on the oxygen supply only.

xvi) Select CMV + PEEP. No audible alarm should sound as the condition of one gas supply only at start up is taken as an intended condition. The 'single gas operation' LED will, however, continue to flash as a reminder that this mode of operation has been selected.

xvii) Select '0'.

xviii) Remove the battery and insert a standard 1.5v AA size battery in its place. Select CMV+PEEP. The alarms should show as in viii) above but the low battery light should also flash.

xix) Select '0'. Refit the original battery. Turn off the oxygen supply and disconnect from the supply connector.

5. Carry out lock off leak test to input supply connections

i) Connect an isolation valve with a calibrated 0-700 kPa (0-100 psi) gauge to the oxygen supply.

ii) Connect the oxygen supply hose to the isolation valve.

iii) Check that the isolation valve is open.

iv) Turn on the gas supply and note the pressure indicated.

v) Close the isolation valve and check that the pressure retained between valve and the ventilator does not drop by more than 20 kPa (3 psi) in 30 seconds.

vi) If the pressure drops faster check that there is no leakage at the connections on the isolation valve, supply hose and ventilator. Also check that there is no leakage of gas from the air hose probe indicating a cross leak. No external leak would indicate an internal leak and the ventilator should be returned to the manufacturer for repair.

vii) Disconnect the oxygen supply and open the isolation valve to purge the hose.

viii) Repeat the test above for the air supply connection.

6. Check the Function Selector switch

(refer to figure 1)

i) Connect a ratePAC (510-A1541) to the Test Lung.

ii) Connect the oxygen probe of the ventilator directly to the oxygen supply.

iii) Turn on the oxygen supply. There should be no alarms.

iv) Select each function in turn and check the following:

a) 0 - No output from the ventilator nor the alarms.

b) CMV+PEEP or CMV+ACTIVE PEEP - Pulsed output, times controlled by TINS and TEXP controls and pressures controlled by Inspiratory Pressure and PEEP/CPAP controls. The 'cycle' LED should flash for 1/10 second each time the pressure rises through 10 x100Pa (10 cmH2O). The 'single gas operation' LED should flash to indicate single gas selection.

c) CPAP - Constant flow output from ventilator, not cycled. Pressure controlled by PEEP/CPAP control. No electronic alarms function during CPAP.

d) IMV+CPAP - Pulsed output as CMV, but CPAP during a longer TEXP time. No electronic alarms function during IMV + CPAP.

v) Check for positive switching, i.e. that there are no indeterminate mid-positions where the function is not clearly indicated by the marking on the panel label.

vi) Turn to '0'. The ventilator should stop functioning and all alarms should cease.

vii) Turn off the oxygen supply.

7. Check calibration of Inspiratory (T_{INS}) and Expiratory (T_{EXP}) Time controls

7a. On Oxygen Only

(refer to Figure 3)

i) Set Oxygen Concentration control to 100% (maximum)

ii) Set PEEP/CPAP pressure control to minimum.

iii) Set Inspiratory Pressure control to 30 x100Pa (30 cmH_2O).

iv) Set Pressure Alarm to 80 x100Pa (80 cmH_2O) maximum.

v) Turn on oxygen supply.

vi) Select CMV + PEEP. The 'single gas operation' LED should flash every 30 seconds and the 'cycle' LED should flash for 1/10 second each time the pressure rises through 10 x100Pa (10 cmH_2O).

vii) Confirm inspiratory pressure on the Patient Pressure Manometer.

viii) Select each of the settings specified on section 12a of the Service Record Sheet.

ix) Record the actual time for each T_{INS} and T_{EXP} setting in the appropriate boxes.

x) Select IMV + CPAP and record the T_{EXP} time in the appropriate box. (The electronic alarm system does not operate during the IMV mode.)

xi) Select '0'.

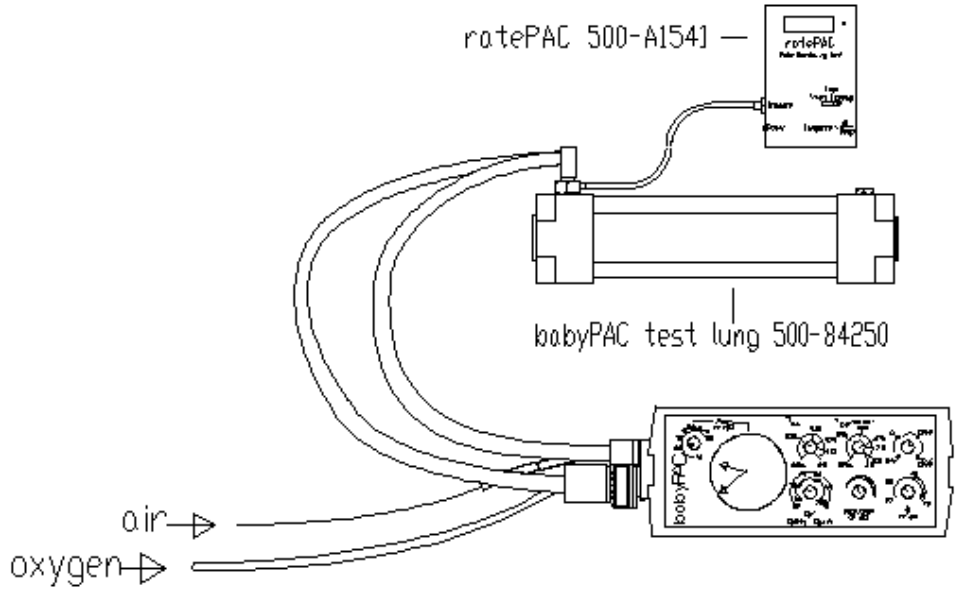

Figure 3

7b. On Oxygen and Air
(refer to Figure 3)

i) With oxygen still connected, reconnect the air supply.

ii) Set the Oxygen Concentration control to 21% (minimum).

iii) Turn on the air supply. The 'single gas operation' LED should not flash.

iv) Select CMV + PEEP. After the initial 60 seconds only the 'cycle' LED should be flashing.

v) Select each of the settings specified on section 12b of Service Record Sheet.

vi) Repeat 12a vii), viii) and ix) above.

vii) Select '0'. All alarms should cease.

viii) Turn off and disconnect the air supply.

ix) Disconnect the ratePAC.

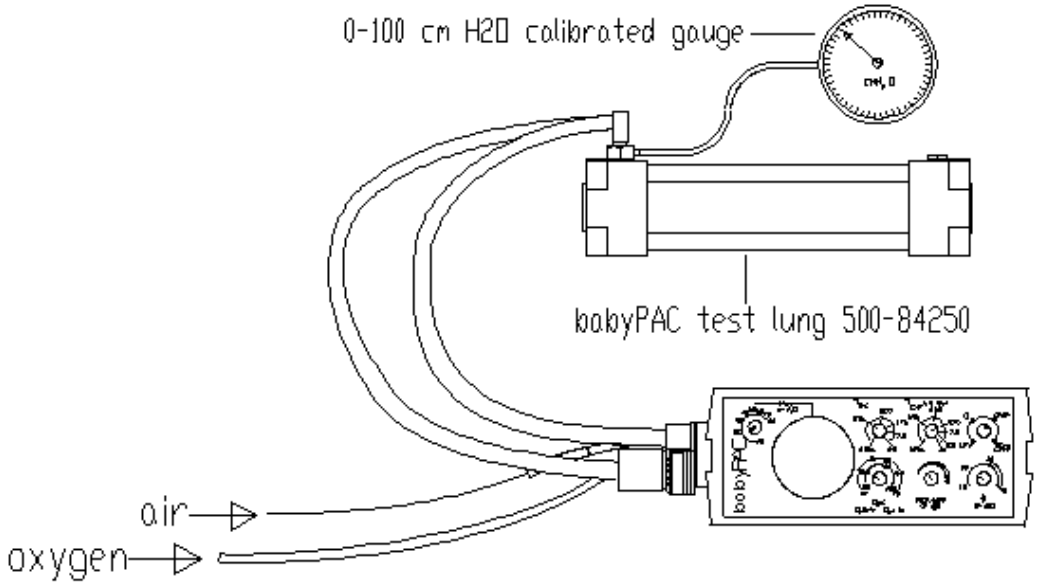

Figure 4

8. Check calibration of PEEP & CPAP Pressure control

(refer to Figure 4)

i) Connect a calibrated 0-100 x100Pa (0-100 cmH_2O) pressure gauge (e.g. 500-82802/2) to the Test Lung.

ii) Set T_{INS} and T_{EXP} at 0.5 secs

iii) Set Pressure Alarm at 80 x100Pa (80 cmH_2O).

iv) Set Inspiratory Pressure at 70 x100Pa (70 cmH_2O).

v) Select CMV+PEEP. The 'single gas operation' LED should flash every 30 seconds and the 'cycle' LED should flash for 1/10 second each time the pressure rises through 10 x100Pa (10 cmH_2O).

vi) Check & record minimum, detent & maximum PEEP on both the calibrated gauge and the Patient Pressure Manometer. When the PEEP level is greater than 10 x100kPa (10 cmH_2O) for longer than 8 seconds, the 'cycle' LED will not indicate but after 8 seconds the Constant Positive Inflation Pressure alarm should activate (see Figure 2). The 'high inflation pressure' LED should flash 2 times per second and a high priority audible alarm should sound, consisting of two bursts of five pulses at a rate of 6 times per minute.

vii) Depress the 'silence' button and the electronic audible alarm should silence for 60 seconds. After this 60-second period has elapsed, depress the button again and the audible alarm should now remain muted. The 'single gas operation' LED will continue to indicate.

viii) Select CMV+ACTIVE PEEP.

ix) Check & record minimum, detent & maximum ACTIVE PEEP on both calibrated gauge and Patient Pressure Manometer.

x) Select CPAP. During CPAP no alarm should operate.

xi) Check & record minimum, detent and maximum CPAP on both the calibrated gauge and the Patient Pressure Manometer.

xii) The difference between the calibrated gauge and the Patient Pressure Manometer should be no more than 2 x100Pa (2 cmH_2O).

xiii) Select '0'.

9. Check calibration of Inspiratory Pressure control

(refer to Figure 4)

i) Select CMV+ PEEP. The 'single gas operation' LED should flash and the 'cycle' LED should flash each cycle.

ii) Set T_{INS} at 2.0 seconds.

iii) Set Pressure Alarm at 80 x100Pa (80 cmH_2O).

iv) Set PEEP/CPAP control to minimum.

v) Set the Inspiratory Pressure successively to minimum, 20 x100Pa (20 cmH_2O), detent and maximum inspiratory pressures and record the readings on both the calibrated gauge and the Patient Pressure Manometer at each setting.

vi) Select '0'.

vii) Reconnect the air supply to the ventilator.

viii) Turn on the air supply.

ix) Select CMV + PEEP. The 'cycle' LED should flash.

x) Repeat v) above.

9. Check calibration of Inspiratory Pressure control (continued)

xi) Disconnect one limb of the Patient Circuit.

xii) After 8 seconds the 'low inflation pressure' alarm should flash and sound. The LED should flash 30 times a minute and the medium priority audible alarm should sound.

xiii) Select '0'.

xiv) Turn off and disconnect the air supply.

xv) Disconnect Patient Circuit, Test Lung and pressure gauge from the ventilator.

10. Check calibration of Oxygen Concentration control on CMV with oxygen supply only (refer to Figure 8)

i) Fit a 22mm hose at least 300mm long, a Backpressure Device (500-A82803) and an Oxygen Monitor (POM 602) onto the output connector of the Control Module.

ii) Connect a 22mm hose, at least 900mm long, to the outlet of the Oxygen Monitor to ensure that atmospheric air cannot reach the sensor during the expiratory phase

iii) Select CMV + PEEP. Both the 'single gas operation' LED and the 'cycle' LED should indicate.

iv) Set a backpressure of 20 x100Pa (20 cmH_2O) using the Backpressure Device.

v) Set T_{INS} to 2.0 seconds and T_{EXP} to 4.0 seconds.

vi) Record the actual oxygen concentrations at the various settings indicated by section 15 of the Service Record Sheet.

vii) Set T_{INS} to 0.25 seconds and T_{EXP} to 0.25 seconds.

viii) Repeat vi) above.

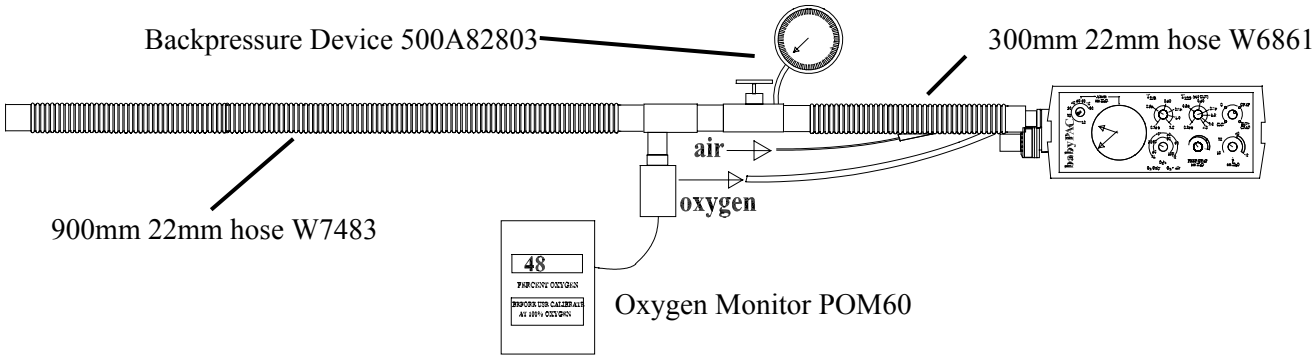

Figure 5

11. Check calibration of Oxygen Concentration control on CPAP with oxygen and air supply (refer to Figure 8)

i) Reconnect and turn on the air supply.

ii) Select CPAP. There should be no audible or visual electronic alarms.

iii) Set a backpressure of 20 x100Pa (20 cmH_2O) using the Backpressure Device.

iv) Check and record oxygen concentrations at the various settings indicated by section 16 of Service Record Sheet.

v) Select 'O'. Turn off and disconnect the air supply.

vi) Remove the Oxygen Monitor and 900mm hose.

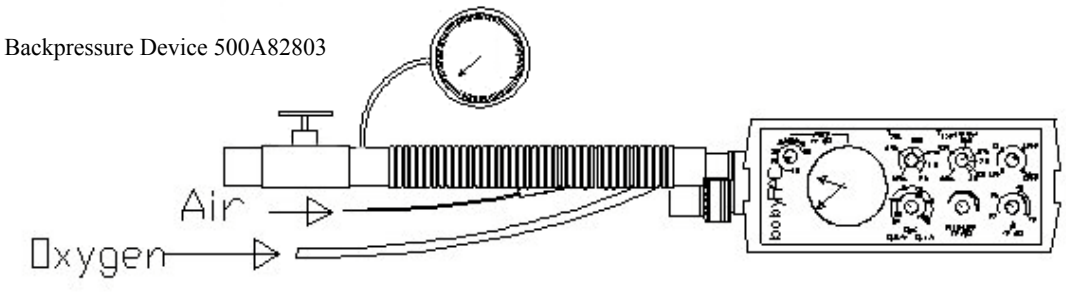

Figure 6

12. Check calibration of Audible High Pressure Alarm control
(refer to Figure 6)

i) Set T_{INS} to 2.0 secs and T_{EXP} to 0.25 secs.

ii) Set the Oxygen Concentration control to 100%, PEEP and Inspiratory Pressure to minimum.

iii) Select CMV + PEEP.

iv) Set the Pressure Alarm control to 12 x100Pa (12 cmH_2O).

v) Close the ball valve of the Backpressure Device fully for one cycle only and read the pressure indicated on the calibrated gauge. The pneumatic High Inflation Pressure Alarm should sound. The 'high pressure' LED should flash at 2 times per second and, 1 second after the pneumatic alarm sounds, the electronic alarm should give two bursts of five pulses of sound at a rate of 6 times per minute. Both alarms should persist for 10 seconds after the condition is last detected. They then should reset.

vi) Open the Backpressure Device fully before resetting the Pressure Alarm control to the next position.

vii) Record the readings at the various settings indicated on section 17 of Service Record Sheet.

viii) Turn off the oxygen supply.

ix) Disconnect the oxygen probe and remove the test equipment.

13. Check the condition and security of mounting box, brackets, clamps and pole mounts

i) Where applicable, inspect the mounting box, bracket, clamp or pole mount attached to, or containing, the Control Module.

ii) Ensure that all socket head fixing screws connecting the Control Module to the bracket, clamp or pole mount are in place and secure. Tighten if necessary.

iii) Check that, in the installed position, the Air Intake Port is not in a confined space such that it may pick up oxygen-rich gas from the Exhalation Valve. It draws in ambient air and any recirculation of exhalation gas will affect the O_2 concentration delivered to the patient. If a confined space is inevitable connect a short length of 10mm bore soft tubing to the outside diameter of the port to duct in fresh air from the nearest convenient point.

14. Attach Service Label

i) Record all repairs, replacements and further comments on the Service Record Sheet 1.

ii) Sign, date and affix a service record label to the Control Module.

iii) Sign, date and affix a service record label to the Regulator Assembly/ies (ensuring the over-pressure vents on the Regulator body/ies are not covered).

15. Report non-critical faults to customer

Any non-critical faults, which do not require immediate corrective action, **must** be recorded on the Service Record Sheet 1 **and** verbally communicated to the customer.

16. Report critical faults to the customer
(including 'Warning Do Not Use' label if no exchange unit is available)

i) Any critical fault or out of calibration readings, which cannot be corrected on site at the time of service, **must** be clearly written on the Service Record Sheet **and** be verbally communicated to the customer.

ii) Should no exchange unit be available affix a 'Warning Do Not Use' label (504-24) to the Control Module and advise the customer to return the unit for repair or service exchange.

17. Obtain an acceptance signature on the Service Record Sheet where applicable.

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SECTION 4: SPARE PARTS

a) babyPAC 100 Ventilator

Description	Part No.
Exhalation Valve Housing	510-1385/CE
Control Knob End Cap (Blue)	W6722/CE
VRV Control Knob End Cap (Red)	W6723/CE
Control Knob End Cap With Line (Black)	W7153/CE
Control Knob End Cap With Dot (Black)	W7155/CE
Pneumatic Alarm Assembly	300-9377/CE
Input Hose (Oxygen)	500-A226/CE
Input Hose (Air)	500-A4881/CE
Single Use Patient Circuit Kit	122004
Air Input Connector	510-A1493/CE
Disc Sintered Filter	W9158/CE
O-ring	W5523/CE
Special circlip	W6487/CE
Oxygen Input Connector	500-A4976/CE
Air Intake Filter Assembly	510-A1399/CE
Conical Sintered Filter	W9151/CE
O-ring	W5520/CE
G1/4 Sealing Washer (MR compatible)	W5582/MRI
Control Knob	W7152/CE
Control Knob for Variable Relief Valve	W7149/CE
Low Pressure Gauge (0-100 x 100Pa)	500-A4832/CE
Battery Retaining Cap	510-A1845/CE
3.6V Battery for use in MR Environment	W269-023
Cylinder valve handwheel	500- A171/CE
Pin-index Yoke Sealing Washer (pack of 3)	500-276/3/CE/MRI

b) Special Equipment and Tools for Periodic Checking of babyPAC 100 Ventilator

Description	Part No.
ratePAC	510-A1541
Pneupac Back-pressure Device with 0-100 x100Pa (0-100 cmH_2O) Pressure gauge	500-A82803
Pneupac calibrated 0-100 x100Pa (0-100cmH_2O) gauge	500-82803/2
Oxygen Monitor	POM602
babyPAC 100 ISO Test Lung C 0.5, R100	500-84250
300 mm long 22mm. dia. Hose	W6861
900 mm long 22mm.dia. Hose	W7483
'WARNING DO NOT USE' label	504-24
Knob Collet Spanner	500-82073
Knob Height Setting Shim	500-84551

APPENDIX A

Product Safety, Transportation and Disposal of Recommended Batteries

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APPENDIX A - PRODUCT SAFETY, TRANSPORTATION AND DISPOSAL OF LITHIUM BATTERIES

Lithium Batteries
Product Safety, Transportation and Disposal
PRECAUTIONS FOR HANDLING AND USE

Lithium battery cells as recommended for use with this device will provide long, reliable and safe service when used correctly. To achieve optimum performance and trouble-free operation, the following precautions should be observed.

ALWAYS take care to fit batteries correctly, observing the 'plus' and 'minus' signs on the battery and appliance.

ALWAYS replace batteries in your equipment with the type and size of battery specified by the manufacturer.

ALWAYS remove dead batteries from equipment and all batteries from equipment your know you are not going to use for a long time.

ALWAYS keep batteries away from small children. If swallowed seek medical advice immediately and contact the subsidiary of the battery manufacturer in you country.

NEVER deliberately short-circuit batteries.

NEVER take apart, crush, puncture or mutilate lithium batteries.

NEVER bring a damaged cell in contact with water. Lithium metal reacts vigorously with water producing flammable hydrogen gas that can cause a fire.

PRECAUTIONS FOR STORAGE

Batteries should be stored at temperatures between 10°C and 25°C with relative humidity not exceeding 65%. To maximise shelf life, excessive temperature cycling and storage at temperatures greater than 25°C should be avoided. Storage of lithium batteries at lower temperatures is possible, providing care is taken in returning the batteries to room temperature prior to use.

Store unused batteries in their packaging and keep away from metal objects which may cause short-circuit resulting in possible leakage, or in extreme cases an explosion.

CHARGING

Lithium batteries are of the primary type and are NOT designed to be recharged. Attempts to recharge these batteries can lead to leakage and possibly an explosion.

No responsibility is accepted by the manufacturer for injury or damage resulting from the cells having been recharged or otherwise abused.

IF PART OR WHOLE OF THE BATTERY IS SWALLOWED
SEEK MEDICAL ADVICE IMMEDIATELY

Note: Lithium batteries are not subject to EC requirements on the classification, packaging and labelling of dangerous substances or preparations (directives 67/548/EEC and 88/379/EEC as amended).

TRANSPORTATION

AIR TRANSPORTATION

Lithium batteries are exempt from IATA/ICAO transport regulations under special provision A45, provided that they meet criteria given below.

ROAD TRANSPORTATION

Lithium batteries are exempt from the ADR regulations under Marginal 2901a, provided that they meet the criteria given below.

RAIL TRANSPORTATION

There are no special requirements for the transportation of lithium batteries under the RID regulations.

SEA TRANSPORTATION

Lithium batteries are exempt from the IMDG code under the special provisions of Page 9033, provided that they meet the criteria given below.

CRITERIA FOR EXEMPTION OF LITHIUM BATTERIES FROM TRANSPORTATION REGULATIONS.

1. Each cell contains not more than 1 gram of lithium or lithium alloy.

2. Each battery contains not more than an aggregate quantity of 2 grams of lithium or lithium alloy.

3. Cells are separated so as to prevent short-circuit.

4. Batteries are separated so as to prevent short-circuit and are packed in strong packaging, except when installed in electronic devices.

5. If a battery contains more than 1 gram of lithium or lithium alloy, it does not contain a liquid gas that is considered dangerous, unless the liquid or gas, if free, would be completely absorbed or neutralised by other materials in the battery.

The lithium batteries recommended in this Manual are covered by this exemption from the above international regulations. For restrictions applying to individual countries, the relevant regulatory authority should be consulted.

REFERENCES

- Dangerous Goods Regulations. Montreal: International Air Transport Association, 1993.

- European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR). 1993 Edition. London: HMSO, 1992.

- Regulations Concerning the International Carriage of Dangerous Goods by Rail (RID). 1990 Edition. London: HMSO, 1989.

- International Maritime Dangerous Goods Code. London: International Maritime Organisation, 1992.

DISPOSAL

DISPOSAL PROCEDURES

As they contain no mercury, lead or cadmium, the disposal of the lithium batteries recommended in this manual is not regulated by European Community Directive 91/157/EEC on “Batteries and Accumulators Containing Certain Dangerous Substances”.

However, individual countries may also establish regulations that cover the disposal of waste batteries. These may be more stringent that EC requirements. Thus, local regulatory authorities should be contacted for their disposal guidelines.

In the absence of specific regulations or guidelines the following is recommended for the disposal of lithium batteries.

Up to five lithium batteries can be disposed of with other general waste.